Test Validation Action Plan

Issue Group: Laboratory Systems

Specific Activity Area being Addressed by this Action Plan: **Role of NVSL and CVB in Developmental Work / Test Validation.** A Laboratory System requires a process for development, validation and implementation in order to gain international acceptance. Regardless of the source of reagents, validation is required to determine test suitability for a particular use. The National Veterinary Services Laboratories transfers appropriate testing technology to networked laboratories for detection, surveillance, exclusion, and international movement purposes.

Safeguarding Review Recommendations Covered:
17. Define the role of the NVSL as the reference laboratory in support of the NSS.
18. Upgrade the capabilities of the NVSL and the CVB for their critical role in the surveillance system.
21. Meet applied research and development needs for the scientifically based NSS.
73*. Seek funding to address the diagnostic and applied research needs for FADD activities, including the establishment and maintenance of Biosafety Level (BSL) 3-AG and BSL 4 laboratory facilities. **(also included under Funding)*
95. Ensure that critical agencies, personnel, and programs for the US diagnostic and applied research infrastructure are superlative, and that this diagnostic and applied research excellence is a critical agency priority for USDA.
121. Utilize previous NVSL reviews in conducting a needs assessment of the National Laboratory System regarding emergency diagnosis and applied research. Implement a plan that supports the immediate and long-term needs of the National Laboratory System.
136. Define and prioritize applied research needs to address wildlife and exotic species issues in animal health emergencies.
139*. Reverse the serious erosion of animal health applied research funding that has occurred in past years. **(also included under Funding)*

Issue Group Findings: Working within the Memorandum of Understanding signed by Animal and Plant Health Inspection Service (APHIS) and Agricultural Research Service (ARS), assign roles to NVSL and CVB for conducting diagnostic developmental work and diagnostic test validation/evaluation, particularly for short-term, emerging needs and tests used within the NAHLN. Rigorous validation is required for international acceptance of diagnostic assays. Personnel and other resources need to be available at NVSL to coordinate developmental diagnostics. When disease experts are not available in-house, a mechanism needs to be developed to consult with outside disease experts for input and advice. ARS will be responsible for developing real-time PCR's for Foot and Mouth Disease, Rinderpest, Contagious Bovine Pleuropneumonia, Lumpy Skin Disease, Classical Swine Fever, African Swine Fever, Highly Pathogenic Avian Influenza, Exotic Newcastle Disease, and Vesicular Stomatitis. NVSL will complete field validation of the assays developed by ARS and progress and issues will be reported to CVB to assist in the potential licensure of any of the assays.

Proposed Actions: ARS and APHIS are collaborating to validate rapid assays for the detection of foreign animal diseases. Validation criteria were developed by ARS and APHIS as well as others. These validation criteria which exceed OIE requirements are being used to validate real time PCR's for CSF and FMDV. Dossiers containing the validation data will be available to review.

1. The template as developed by APHIS, ARS, and others should be employed for the validation process and incorporated in the NAHLN Uniform Methods and Rules (UM&R).

2. A plan to review the dossiers for AI, END, CSF and FMDV needs to be developed and implemented. Groups composed of APHIS, ARS, and other scientists need to be formed to review the dossiers and make recommendations for adjustments to the validation criteria.

3. This process should be applied to all other diseases/assays included in the NAHLN.

Implementation Plan:

1. Incorporate template in NAHLN UM&R
   Responsible individual/group: NAHLN Coordinator
   Timeline: By January 2005

2. Form disease/technique specific groups of APHIS, ARS, and other scientists to review the dossiers after data collection is completed and make recommendations for assay use and adjustments to the validation criteria
   a. Review the dossiers for AI, END, CSF and FMDV.
      Responsible individual/group: NAHLN Coordinator
      Timeline: By January, 2005; and others as they are assembled

3. Apply validation process to new assays considered for the NAHLN
   Responsible individual/group: NAHLN Coordinator
   Timeline: Ongoing

Other Key Players: ARS, AAVLD member laboratories, disease specific research scientists/institutions.

Resources Needed

Travel expenses for dossier review groups – $20,000 per year

Statutory/Regulatory Impacts
No impacts currently foreseen.

Political Sensitivities
In order to adequately support and effectively administer the validation process, NAHLN laboratory participation and test reagent selection may need to be limited. The rigorous criteria for the selection of participating laboratories and deployment of assays need to be transparent as incorporation into the network brings responsibilities and funding to the laboratories that are highly visible to stakeholders, political and business interests.

Being prepared with properly validated assays and laboratory surge capacity would facilitate the national response and recovery in an adverse animal health event.

Sequencing
The Safeguarding Lab System group's action plans on quality assurance and test validation should be executed in parallel with NAHLN development.

Partnering/Cooperation/Communication:
Assay selection and validation processes involve obtaining input from partners which include States, industry, other Federal and international agencies.

Expected Outcome and Performance Indicators:
Validation templates will be incorporated into the NAHLN UM&R

All completed dossiers are reviewed within three months.

Deployment of the validated tests.

Linkage to the VS Strategic Plan:

The following Goals and Objectives are supported by the proposed actions.

Objective 2.6 – Improve laboratory diagnostic services, products and training to support animal disease surveillance.

Objective 3.2 – Ensure the nationwide availability of adequate laboratory capacity to support animal disease investigations and control and eradication programs.

Objective 4.4 – Improve diagnostic testing associated with the marketing of animals and animal products.